DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 6 2002

02 SEP -9 P1:34

Sidney M. Wolfe, M.D.
Director Health Research Group
Public Citizen
1600 20th Street, NW
Washington, DC 20009

Re: Docket No. 02P-0120/CP1

Dear Dr. Wolfe:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated March 19, 2002, requesting the immediate ban of Meridia (sibutramine) due to safety concerns.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

02P-0120

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